Notice of Allowability	Application No.	Applicant(s)	
	09/380,015	KORTH ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *31 December 2003*.

2. ☒ The allowed claim(s) is/are *77,78,80-86,88,90,93,108,109 and 113*.

3. ☒ The drawings filed on *31 December 2003* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Toren on February 24, 2003.

The application has been amended as follows:

In the specification, on page 1, after the title, the prior amendment is deleted and the following the continuing data information is inserted

-- This application is the U.S. national phase under U.S.C. § 371 of international application No. PCT/EP98/00917, filed 18 February 1998.--

The claims have been amended as follows:

77. (currently amended) An isolated monoclonal antibody or a fragment thereof, wherein said antibody and said fragment are capable of binding only to native disease-specific prion protein (PrP^{Sc}) and not to native normal prion protein (PrP^{C}) in an antigen-antibody complex.

78. (currently amended) An isolated monoclonal antibody according to claim 77 capable of recognizing at least one of 3 distinct arrays on the disease-specific prion protein (PrP^{Sc}) with amino acid sequences according to SEQ ID NOs: 7, 8 and 9.

79. (cancelled)

80. (currently amended) An isolated monoclonal antibody according to claim 77 wherein the ~~prion protein~~ PrP^{Sc} is soluble.

81 . (currently amended) An isolated monoclonal antibody according to claim 77 wherein the ~~prion protein~~ PrP^{Sc} is insoluble.

82. (currently amended) An isolated monoclonal antibody according to claim 77 wherein the ~~prion protein is~~ antibody is produced using a recombinant prion protein.

83. (currently amended) An isolated monoclonal antibody according to claim 77 wherein the ~~prion protein is~~ antibody is produced using a reduced recombinant prion protein.

84. (currently amended) An isolated monoclonal antibody according to claim 77 wherein the ~~prion protein is~~ antibody is produced using an oxidized recombinant prion protein.

85. (currently amended) An isolated monoclonal antibody which comprises an epitope binding fragment of any one of the monoclonal antibodies according to claim 78, said antibody specifically binding to native PrP^{Sc} without binding to native PrP^{C}.

86. (currently amended) An isolated monoclonal antibody according to claim 77 coupled to other molecules ~~especially~~ including fragments of other antibodies, enzymes or organic chemical compounds.

87. (cancelled)

88. (currently amended) A hybridoma cell line ~~capable of~~ producing an isolated monoclonal antibody according to claim 77.

89. (cancelled)

90. (previously amended) A hybridoma cell line according to claim 88 deposited under DSM ACC2298 capable of producing an isolated monoclonal antibody which recognizes 3 distinct arrays on the prion protein with amino acid sequences according SEQ ID NOs'. 7, 8 and 9 said antibody specifically binding to native PrP^{Sc} without binding to native PrP^{C}.

91 - 92. (cancelled)

93. (previously amended) An isolated monoclonal antibody produced by a hybridoma cell line according to claim 90.

94 - 107. (cancelled)

108. (currently amended) A test kit for the diagnosis of prion diseases comprising one or more isolated monoclonal antibodies according to claims 77, purified recombinant bovine PrP protein in reduced or oxidized form or in form of a mixture thereof, at least one nitrocellulose sheet[s], at least one microtiter plate[s]coated or covalently linked with isolated monoclonal antibody according to claim 77, an antibody that is coupled with an enzyme and, ~~its~~ the substrate of said enzyme for a detection reaction, proteinase K, blocking buffer, homogenization buffer and ~~a detailed description of~~ instructions for how to perform the test.

109. (currently amended) A test kit according to claim 108 ~~comprising a~~ wherein said nitrocellulose ~~membrane~~ sheet is in the dipstick format coated with ~~an~~ isolated monoclonal antibody according to claim 77, and the kit further comprises a dilution buffer, a solution containing an isolated monoclonal antibody according to claim 77, coupled to colloids evoking a coloring reaction when present in an antigen-antibody complex. ~~, and a detailed description of how to perform the test.~~

110-112. (cancelled)

113.(currently amended) A ~~pharmaceutical preparation for the therapy and prevention of prion diseases~~ composition comprising an isolated monoclonal antibody or fragments thereof according to claims 77 and a pharmaceutical carrier, said antibody specifically binding to native PrP^{Sc} without binding to native PrP^{C}.

114-117. (cancelled)

The following is an examiner's statement of reasons for allowance: The prior art rejections are withdrawn in view of Applicant's submission of the Declaration by Dr. Glenn Telling.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

The official fax phone number for the organization where this application or proceeding is assigned is 703-872-9306; for informal communications please the fax phone number will change to 571-273-0912

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER